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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HINES, JANA A

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/002,690	Applicant(s) CAVANAUGH, PHILIP GERARD	
	Examiner JaNa Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 97-116 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 97-116 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. The amendment filed December 26, 2007 has been entered. The examiner acknowledges the amendments to the specification. Claims 1-96 have been cancelled. Claims 97-99, 101, 107, 109-115 have been amended. Claim 116 has been newly added. Claims 97-116 are under consideration in this office action.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 116 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 116 is drawn to the method of claim 97 step [f], wherein the applying to said membrane further comprises an initial applying to said membrane of a block solution, comprising a solution containing agents which occupy all non-occupied sites on said membrane, thereby preventing the binding of the antibody specific for said hapten, to sites other than said membrane-bound hapten-ligand.

Neither the originally filed specification nor originally presented claims provides support for this method step, moreover, there is no support in the originally filed application for the method further comprising an initial applying to said membrane of a block solution, comprising a solution containing agents which occupy all non-occupied sites on said membrane, thereby preventing the binding of the antibody specific for said hapten, to sites other than said membrane-bound hapten-ligand. Applicant did not point to support in the original specification for support. Moreover, applicant failed to specifically point to the method steps. Thus, there appears to be no teaching of the newly recited method. Therefore, it appears that the entire original specification appears to fail to recite support for the newly recited method step. Therefore, applicants must specifically point to page and line number of the original specification for support of the newly added amendment. Therefore, the new claim incorporates new matter and is accordingly rejected.

Claim Objections

3. Claims 97-116 are objected to because of the following informalities:

a) Claims 97-99, 101 and 115 delineate the individual steps by bracketing the sub-step. For instance [a]. The other dependent claims identify their associated claim having brackets also; for instance Claim 97[a]. However, the brackets normally show the information is being deleted. Thus information being deleted is shown with the strike-through or brackets, while new information is shown with underlining. Thus it is

suggested that applicants delineate the claims with parenthesis and not brackets, unless applicants is deleting such information.

b) Claim 99 recites two (b) steps. It is suggested that the later (b) step be delineated as step (c).

Therefore clarification is required to overcome the objections.

Claim Rejections - 35 USC § 112.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 97-115 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 98 recites “thereby verifying the specific binding of said hapten-ligand to said surface”. However the “thereby” does not make the verification an active method step. It is suggested that the thereby language be removed and be replaced such that the verification is an active step of the method.

b) Claim 110 recites alternative limitations which are improperly expressed. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of

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alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language. It is suggested that the claim recites "...slot blotting **and** western blotting"

c) The claim scope is uncertain since the trademark NYTRANTM or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a particular material, i.e. NYTRANTM, thus the identification is indefinite. Furthermore, the use of trademarks is improper since products identified by trademarks are within the sole control of the trademark owner and are subject to change by said owner at their discretion. It is suggested that a description such as charged nylon membrane be used instead.

d) Claim 113 recites alternative limitations which are improperly expressed. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group recites members as being "selected from the group consisting of A, B and C". Another acceptable form recites "selected from 1, 2, 3, or 4." Applicant may correct this by amending the claim to recite the appropriate language.

Claims 97-116 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The claims recites "whereby" clauses throughout the claims. It is noted that such interpretive clauses do not recite any additional active method steps, but simply state a characterization or conclusion of the results of those steps. Therefore, such "whereby" clauses are not found to further limit the method defined by the claims. Furthermore, the "whereby" clauses fails to add patentability or substance to the claims. Thus, it is suggested that the claims positively recites the intended method step. For instance, claim 97(h) could recite "...lysate, quantifying the amount of the membrane..."

Conclusion

5. Claims 97-115 are not rejected under prior art but are rejected under 112 1st and 2nd paragraph.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JaNa Hines whose telephone number is (571)272-0859. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JaNa Hines/
Examiner, Art Unit 1645

/Mark Navarro/
Primary Examiner, Art Unit 1645